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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF CHRISTOPHER S. MORRIS, M.D.**

Plaintiffs respectfully submit this Reply Memorandum in Support of Plaintiffs' Motion to Exclude the Opinions and Testimony of Christopher S. Morris, M.D.

I. INTRODUCTION

Christopher S. Morris, M.D., is an interventional radiologist who is being offered as an expert by Bard. Among Dr. Morris's opinions, he offers that Bard's filters are safe and effective, that imaging of patients pre-retrieval is unnecessary, that complications have no bearing on the decision to remove filters, and that filters that have been in place long-term do not need imaging or medical monitoring follow-up. The Court should exclude Dr. Morris's opinions because his sweeping and unsupported claims about the safety and efficacy of Bard filters, as well as claims about imaging and retrieval are outside the medical mainstream and are based on an unsound methodology.

Bard bears the burden of proving that Dr. Morris' testimony is admissible. *See, e.g., Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). Bard has failed to carry its burden. In their opening brief, Plaintiffs showed that Dr. Morris disregarded a range of peer-reviewed studies identifying the risks of Bard IVC filters, ignored literature recognizing the need for medical imaging during patient follow-up, criticized, without basis, the need to diagnose complications as part of a follow-up program, and overlooked the needs of patients with long-indwell filters. Plaintiffs demonstrated that Dr. Morris did not base his opinions regarding the safety of IVC filters and the need for follow-up on sufficient facts or data and did not utilize sound methodology, that he ignored relevant medical literature, and refused to even consider Bard's internal information and data. Plaintiffs also demonstrated that Dr. Morris did not substantiate his opinions regarding the use of medical imaging during follow-up and whether asymptomatic patients require medical imaging, ignoring the medical community's guidance and again disregarding relevant medical literature.

Bard's response fails to justify these failures of methodology and approach, and Dr. Morris's testimony should be excluded.

II. ARGUMENT

A. Dr. Morris Does Not Utilize Sound Methodology in Forming his Opinions About Safety and the Need for Follow-Up Imaging.

Federal Rule of Evidence 702 permits a witness to give expert testimony if "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. In making his opinions about the safety of Bard IVC and about whether imaging during follow-up is needed for purposes of finding complications during follow-up, Dr. Morris did not rely on sufficient facts or data and did not utilize reliable principles and methods because he selectively ignored medical literature finding increased fracture rates and ignored Bard's own internal data.

1. Dr. Morris Did Not Adequately Consider the Medical Literature.

Dr. Morris opines that Bard IVC filters are safe and effective and that imaging is not necessary to identify complications.[1] Bard's attempt to show that Dr. Morris adequately reviewed the relevant medical literature (Defendant's Opposition, ECF No. 7800 (hereinafter "Br.") at 6-8) in forming these conclusions fails. Plaintiffs demonstrated, and his testimony shows, that Dr. Morris subjectively dismissed or ignored swaths of literature demonstrating the increased long-term fracture rates of Bard IVC filters.[2] Meanwhile, Dr. Morris cherry-picked articles with only short-term follow-up in

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[1] Ex. 3, MDL Rep. at 13, 21.

[2] Q. And nobody has criticized [the An study] in the peer-reviewed literature since it's been published, to your knowledge, have they?
A. I haven't looked for that specifically, so I don't know.
Ex. 4, Morris Dep. at 187:2-6.
Q. Nobody, to your knowledge, has published any critique of the results of [the Tam] study, have they?
A. I haven't looked for those, so I don't know.
Id. at 188:6-8.
Q. You're aware that the Nicholson study that you're critical of has been relied upon and cited by a number of experts in the field in papers that they have published in the peer-reviewed literature, right?

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an effort to minimize the apparent fracture rates.[3] Dr. Morris let his own subjective views—even describing complication concerns as "melodrama" – color his view of the literature when he formed his opinions; he did not appropriately consider the medical literature identifying the risks of Bard IVC filters, especially the increasing risks over time.[4] When an expert "reaches his opinion by first identifying his conclusion ... and then cherry-picking observational studies that support his conclusion," that opinion "does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good

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A. Unfortunately, it's all that is out there. That's what's available.
Q. Am I correct in what I just stated?
A. I think that's true, yes. Sad but true.

Id. at 189:21-190:4.

Q. You now have a section following this where you talk about frequently studied -- cited studies of low fracture complications for IVC filters, right?
A. Correct.
Q. And your paper cites to the Cantwell study?
A. Yes.
Q. Right? It cites to the Binkert study?
A. Yes.
Q. Right? The Mitsunaga study?
A. Yes.
Q. The Damascelli study?
A. Yes.
Q. The Charles study?
A. Yes.
Q. Those studies are all studies without long-term follow-up; isn't that correct?
A. That's --
MR. ROGERS: Object to the form.
A. That is true.

Ex. 4, Morris Dep. at 191:21-192:15.

[4] Q. You -- you agree with me that that's a legitimate question that doctors have about patients with embedded -- with implanted filters?
MR. ROGERS: Object to the form.
A. I think with all the melodrama that has occurred in this whole -- related to all this -- all these issues, that patients are definitely concerned about the status of the filter in that situation, yes.
Q. Is the Kalva paper melodrama?
A. No. But when we turn on the nightly news and we hear, you know, advertisements about filter injuries and all that, that creates an aura of concern among patients, yes.

science.'" *See In re Bextra & Celebrex Mktg. Sales Practices & Prods. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007).

Bard attempts to justify Dr. Morris's dismissal of studies finding increased complication rates over time, asserting that he gave reasons for this dismissal, but those justifications fail. Br. at 7. For example, Bard argues that Dr. Morris believed the An, *et al.*[5] authors "may have inappropriately used numerators and denominators with different prevalence calculators" which made the fracture rate "artificially high." *Id.* Yet Dr. Morris did not cite independent evidence, nor any peer-reviewed literature, that ever criticized the An study for this reason or that disagreed with its findings of high fracture rates and increasing fracture rates over time. He conceded in his deposition he was unaware of such evidence or literature.[6] Dr. Morris also ignored the fact that the An study, like other studies Plaintiffs cited finding increased fracture rates,[7] have been cited

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[5] All Exhibit references are to those attached to Plaintiffs' original motion, ECF No. 7320: See Ex. 7, Tianzhi An, MD, et al., *Prevalence and Clinical Consequences of Fracture and Fragment Migration of the Bard G2 Filter: Imaging and Clinical Follow-up in 684 Implantations*, 25 J. Vasc. Interv. Radiol. 941 (June 2014).

[6] Q. And you're not aware of anybody that's been critical in -- in any published submission to any journal regarding the conclusions of the An paper, are you?

A. "I have not known of any of those. I did not specifically look for any of those.

Ex. 4, Morris Dep. at 187:2-6;

Q. So you don't -- you're not aware of anybody that has been critical of the use of the Kaplan-Meier survival estimate as it was used in this Tam study to conclude that there was a five-year fracture rate of 40 percent?

A. I believe a lot of experts would argue that the way it was used here would not be that -- would not be scientifically valid to a high degree because -- I think of the reasons I cited here, you know, high censored -- high number of censored events. The fudge factor is a little -- little high here.

Id. at 187:13-23.

[7] *See, e.g.*, Ex. 7, Tianzhi An, MD, et al., *Prevalence and Clinical Consequences of Fracture and Fragment Migration of the Bard G2 Filter: Imaging and Clinical Follow-up in 684 Implantations*, 25 J. Vasc. Interv. Radiol. 941 (June 2014); Ex. 8, Matthew D. Tam, MD, et al., *Fracture and Distant Migration of the Bard Recovery Filter: A Retrospective Review of 363 Implantations for Potentially Life-Threatening Complications*, 23 J. Vasc. Interv. Radiol. 199 (Feb. 2012); Ex. 9, William Nicholson, MD et al., *Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade*, Arch. Intern. Med., at E3 (Aug. 9, 2010); Ex. 10, Jeffrey E. Hull, MD et al., *Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration*, 20 J. Vasc. Interv. Radiol. 52 (Jan. 2009).

to and relied upon by multiple peer-reviewed publications. This too he conceded at his deposition. Ex. 4, Morris Dep. at 189:18-190:10. Dr. Morris cherry-picked studies with short-term follow up as "evidence" of the safety of Bard IVC filters, while subjectively disagreeing with the findings of the peer-reviewed studies that demonstrate high complication rates over increasing periods of indwelling time.[8]

Tellingly, the only study whose findings Dr. Morris agreed with, and to which Bard characterizes as a long-term study, is Mitsunaga, *et al.*,[9] and Bard relegates that discussion to a footnote. See Br. at 8, n.7. First, the Mitsunaga authors acknowledged the validity of studies such as Nicholson *et al.*, Vijay *et al*., and Tam *et al.*, which found high complication rates in Bard IVC filters.[10] Second, the Mitsunaga authors specifically stated that "there was no formal plan or protocol in place for follow-up in these patients during the study period" and therefore they could not appropriately identify complications.[11] Furthermore, the Mitsunaga study was primarily conducted on cancer patients, and most of those patients died within 6 months of filter placement.[12] As such, it should not realistically be considered a long-term study as Bard proposes. Moreover,

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[8] Q. And in the medical literature, when somebody publishes a study, there's a mechanism for other experts in the field to -- to comment if they agree or disagree by writing their own opinions and getting those opinions published, either in the form of a letter to the editor of the journal or some other type of communication in the professional literature, correct?
A. Correct.
Q. And so if you disagreed, as you claim to here in your testimony, with the conclusion of the five-year fracture rate at 40 percent, there was -- there was an avenue for you to publish your opinion about that, right?
MR. ROGERS: Object to the form.
A. Theoretically, yes. That -- that – my opinion would then have to be accepted by the peer review process just like everything else. These journals just don't publish any -- any letter that they ever receive.
Q. Of course.
A. It goes through a process to get to the state of publication.
Ex. 4, Morris Dep. At 185:17-186:15.

[9] *See* Ex. A to Br., Mitsunaga, et al., *Fracture Rate and Serious Complications of Vena Cava Filters*, 3 Open J. of Radiol. 85-90 (June 2013).

[10] *Id.* at 88.

[11] *Id.* at 89.

[12] *Id.*

Dr. Morris himself agreed that Mitsunaga was a short-term study. Morris Dep. at 191:21-192:15. Bard's contention that this study (and only this study) is an example of long term follow-up data relied upon by Dr. Morris is a glaring indicator that long-term studies that find Bard's IVC filters to be safe do not exist. Meanwhile, numerous studies that have been cited to by the FDA and the medical community identify increasing complication rates the longer that Bard IVC filters remain indwell. Because Dr. Morris selectively ignored these studies, his opinions should be excluded.

2. Dr. Morris's Opinions Are Not Based on Sufficient Facts or Data and Are Not Reliable Because He Selectively Ignores Bard's Internal Information.

Bard argues, without basis, that Dr. Morris relied on sufficient underlying facts or data in forming his opinions despite Bard's refusal to show him, and Dr. Morris's refusal to even look at, internal company documents. See Br. at 8-11. Evaluation of an expert's opinion testimony "requires consideration of the overall sufficiency of the underlying facts and data, and the reliability of the methods, as well as the fit of the methods to the facts of the case." *United States v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir.2007). An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y.2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; s*ee also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)) "Reliance on literature and experience is not dispositive" where the court must also ensure that the expert has reliably applied the methodology to the facts of the case with "the same level of intellectual rigor that characterizes the

practice of an expert in [that] field." *Trevino v. Boston Sci. Corp.*, No. 2:13-CV-01617, 2016 WL 2939521, at *12 (S.D.W. Va. May 19, 2016) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). Where there is no indication of the reasoning and methods underlying an expert witness's conclusion, the Court cannot make the necessary findings of reliability and utility to a fact-finder under Fed. R. Evid. 702. Such conclusions are properly excluded. *See Claar v. Burlington Northern R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994).

Bard incorrectly argues that courts disapprove of medical experts' reliance on internal company documents.[13] *See* Br. at 10-11. Rather, internal documents often help the expert develop and reinforce their opinions. *See, Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *15 (S.D.W. Va. Feb. 7, 2015) ("Dr. Raybon has properly used Bard's internal documents to develop and reinforce his opinions rather than to narrate Bard's corporate conduct. Furthermore, many of the internal documents relied upon by Dr. Raybon could stand alone as medical research and literature."); *In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, 711 F. Supp. 2d 1348, 1368 (M.D. Ga. 2010) ("[T]he experts' reliance on the journal articles and Mentor's internal documents does not diminish the weight that the Court gives to the experts' opinions, assuming that the opinions are otherwise sufficiently reliable."). Bard cites *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 426 (S.D.N.Y. 2016), contending that the court there did not exclude the defendants' expert's testimony merely because it contradicted statements made by the defendants' employees. *See* Br. at 7-8. Plaintiffs are not suggesting that Bard's internal documents are important only because they

[13]The court in *Soldo v. Sandoz*, 244 F. Supp. 2d 434, 64 (W.D. Pa. 2003), excluded a causation opinion not merely because it was based on internal documents, but because the methodology for making "causality assessments" was not adequately described in the documents. The courts in *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) and *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1046, 1052-53 (S.D. Ill. 2001) both excluded causation opinions because they were based on out of context statements lifted from internal memoranda, that when placed in context, indicated a different conclusion than the experts asserted.

contain conflicting statements to Dr. Morris's testimony, but that the documents contain information and data that is necessary for Dr. Morris to opine as he does on Bard's IVC filters. The internal documents here contain, among other things, years of failure analysis and testing data which provide the best source of information regarding the safety of Bard's IVC filters. Thus, the facts here are more similar to *Wise v. C.R. Bard, Inc.*, where the court found that internal documents would be needed to reinforce the expert's statement and could stand alone as medical research and literature. *See* 2015 WL 521202, at *15.

Bard suggests that practicing medical doctors have no need to see internal documents in the ordinary course of their practice, and therefore Dr. Morris had no need to see Bard's internal documents when forming his opinions. *See* Br. at 9. Bard's argument ignores the obvious distinction between the sweeping opinions about device efficacy that Dr. Morris is offering and what a "practicing medical doctor" would typically make. For instance, Dr. Morris opines that Bard's IVC filters are safe and effective based on his "review of the available literature and his personal experience." Ex. 3, MDL Rep. at 21. Setting aside that he selectively ignored the available literature recognizing the dangers of Bard IVC filters, a practicing medical doctor cannot accurately assess safety without reviewing all the available information. He testified that in doing an evaluation of IVC filters, he would want to know about evidence that a filter had a structural weakness or a high incidence of fracture. Ex. 4, Morris Dep. 199:3-200:3. Yet he stated that he would never want to know about Bard's internal studies, such as Bard's comparisons of its filters to competitors' products or failure analyses. He cannot have it both ways.

Bard's other proffered justifications for Dr. Morris failure to review internal documents also fail. Its assertions that bellwether plaintiffs' implanting doctors did not review Bard internal information either are irrelevant. Those doctors were testifying with regard to facts and circumstances with regard to specific patients' treatments; they were not expounding, like Dr. Morris, on the overall level of safety of Bard's filters.

Meanwhile, Plaintiffs' experts' reports demonstrate that Bard's retrievable filters are not safe and should not have been placed on the market based on a broader review of evidence that includes Bard's internal documents. Yet Dr. Morris seeks to criticize their opinions without reviewing the same information. For example, Dr. Morris criticizes Plaintiffs' experts Drs. Kinney Roberts, and Kalva, who find that Bard used insufficient data to support the market launch of certain filters. Ex. 3, MDL Rep. at 20-21. Dr. Morris notes how their report analyzes internal Bard documents, including communications and bench top testing, and that he never reviewed that information. *Id.* at 20. Yet without reviewing these documents himself, however, Dr. Morris opines that their report does not tell an "important story" about the innovation of Bard IVC filters. *Id*. Dr. Morris then concludes that Bard's method of technological improvement may be interpreted as "quality improvement." *Id.* In making this assessment, Dr. Morris ignores extensive details gleaned from the underlying documents and lacks the broader frame of reference within which Plaintiffs' experts made their opinions. Dr. Morris points to no evidence of Bard's reasoning behind its changes to its filters which would support his opinion. He also makes no assessment of the safety concerns that Bard considered during its decision-making. Rather than request or review the relevant documents or data, he willingly ignored them.

Bard's internal information serves an important basis for determining the overall complication rates of Bard's IVC filters, relative safety, and the necessity of a monitoring protocol. Reliance on literature and experience is not dispositive here because the court must also ensure that the expert has reliably applied his methodology to the facts of the case with "the same level of intellectual rigor that characterizes the practice of an expert in [that] field." *Kumho*, 526 U.S. at 152. Dr. Morris's opinions cannot survive because he admitted that he has "never received confidential internal manufacturer communications, memoranda, in-house bench top and animal research, electronic mail, PowerPoint presentations, or product documents from Bard." MDL Report at 27. Such opinions are not reliable.

The Court in *Trevino* came to the same conclusion in a closely analogous situation in which a party's expert did not review the relevant internal documents. *See, Trevino*, 2016 WL 2939521, at *12-13. The *Trevino* court held that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from [the expert's] methodology" and "[w]ithout any reliable, demonstrated knowledge of [the defendant's] internal design procedures, [the expert] cannot substantiate his opinion that these procedures were departures from the norm, not followed by [the defendant], or lacking in any way." *Id.* at 13. Without properly assessing Bard's internal information, Dr. Morris's methodology lacks sufficient facts or data to sufficiently form an opinion about Bard's IVC filters' safety and effectiveness and/or to rebut Plaintiffs' experts' opinions thereto. Therefore, Dr. Morris's opinions should be excluded.

B. Dr. Morris's Opinions About Imaging and Follow-Up Are Unsubstantiated and Unreliable.

1. Bard's Argument that the SIR Reporting Standards do not Set Forth Follow-up Standards Requiring Imaging is Unfounded.

Plaintiffs' opening brief showed that Dr. Morris failed to recognize key literature that suggests that imaging should be used during a follow-up program. In opining that imaging should not be used in such a program, Dr. Morris claimed that "no authoritative society or organization has specifically recommended imaging as part of a surveillance or medical monitoring program regarding [IVC filters]." Ex. 3, MDL Rep. at 16. Dr. Morris's opinion ignored several Reporting Standards that Bard cites to in its own IFUs which suggest that imaging should be used as a minimum part of a follow-up program. In ignoring basic documents that Bard itself relies upon in the same subject area, Dr. Morris failed to base his opinion "upon sufficient facts or data" and failed to use reliable principles and methods" as applied to the facts of this case. See Fed. R. Evid. 702.

In trying to buttress Dr. Morris's opinion, Bard attempts to parse the Reporting Standards in a manner that is in tension with the language of the standards themselves. Bard argues that the Reporting Standards are not to be followed by clinicians, and instead should only to be used as a guidance for physicians reporting IVC usage in medical

literature. Br. at 14-17. Although Bard could not point to anything in these Reporting Standards directly stating that their guidance are exclusively for medical literature use, Bard nevertheless makes vague claims that the "context" within all of these is "clear" in that they are *only* for use in clinical studies. *Id.* at 14-15.

The text of Reporting Standards is clear about their purpose. The Reporting Standards state that the reason behind the publication of these standards is due to the "increased interest in non-permanent vena cava filters, with both increased research *and clinical use of these devices*."[14] Nowhere do any of the standards state that they are *only* to be used in research. In fact, Dr. Morris himself asserted that use of these reporting standards explicitly for clinical studies was "just … one of the ways to interpret … the meaning of [these standards]. Morris Dep. at 264:1-8. Thus, Dr. Morris clearly contradicts himself when he claims in his reports that no authoritative society or organization recommends imaging as part of a surveillance or medical monitoring program. See Ex. 3, MDL Rep. 16; Ex. 1, Class Rep. 17. Such a contradiction, about a fundamentally important piece of literature, calls into question Dr. Morris's basis for his opinion that imaging should not be part of a follow-up or monitoring program.

Bard nonsensically argues that the Reporting Standards only specify using imaging for permanent filters. Br. at 15-16. The earlier 1999 and 2003 versions of the Reporting Standards specifically use the phrase "minimum objective testing" when recommending imaging of the filter during follow-up. Bard latches onto this language, arguing that the 1999 and 2003 versions of the standards are only applicable to permanent filters, and because this "minimum objective testing" quote is only in these earlier versions, SIR necessarily could not have meant that imaging would be recommended for follow-up of Bard retrievable filters. Br. at 15-16. Although Bard retrievable filters were not on the market in 1999, the Bard Recovery filter was certainly on the market with a retrievability indication when the 2003 Reporting Standards were published.

[14] *See, e.g.*, Ex. 19, Steven F. Millward FRCPC et al., *Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters*, 16 J. Vasc. Interv. Radiol. 441, 441 (2005).

Furthermore, the 2003 Reporting Standards do in fact contain sections specifically addressing "Temporary and Optional Filters" which urge that follow-up assessment for optional filters be performed according to the general recommendations for all filters, including the same "minimum objective testing."[15] The 2003 standards also recommend that follow-up assessments consider "Additional Reporting Criteria for Temporary and Optional Filters" which specify additional procedures for retrievable filters such as determining complications during removal.[16] It is plainly wrong for Bard to suggest that these guidelines are only for permanent filters and that imaging is not recommended for retrievable filters.

Bard also incorrectly suggests that because the Reporting Standards contain references to recording data in clinical studies, it necessarily means that the follow-up recommendations are not to be used as guidance for practicing physicians. Br. at 16-17. It is indisputable that Bard itself cites these Reporting Standards as references in its own IFUs when suggesting that follow-up is necessary for its retrievable IVC filters. For example, the Bard Denali IFU states: "Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive 'routine follow-up' subsequent to the placement of the device." Ex. 17 at 3, Bard Denali IFU. Bard then cites directly to both the 2003 and 2005 Reporting Standards, both of which recommend that imaging be used during follow-up. *Id.* Dr. Morris's failure to recognize Bards own IFU recommendations, along with his unwillingness to acknowledge literature recommending that imaging should be used during follow-up, render his opinions unreliable and therefore his opinions should be excluded.

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[15] Ex. 18, The Participants in the Vena Caval Filter Consensus Conference, *Recommended Reporting Standards for Vena Caval Filter Placement and Patient Follow-Up*, 14 J. Vasc. Interv. Radiol. 427, 429 (2003) ("Reports for [optional] devices should include all the information listed above and also those factors particular to these devices (Table 6).").

[16] *Id.*

2. Bard Mischaracterizes the Literature.

In their opening brief, Plaintiffs showed that Dr. Morris subjectively disregarded certain important articles when making his opinions, including articles by Duffett and Kuo. *See* Ex. 4, Morris Dep. at 171:9-172:20; 188:13-189:17; 191:21-192:24. In response, Bard argues that those articles *support* Dr. Morris's opinions that medical imaging is not needed in a patient follow-up program for the purpose of finding complications, Br. 17-19, but misinterprets those articles.

For instance, Bard cites Duffett, *et al*., arguing that this article supports Dr. Morris's opinion that imaging should only be used during follow-up of IVC filter patients if their complications are symptomatic. Br. 17-18. Bard's suggestion misreads the article. The Duffett article explains that a "growing body of evidence … suggests that IVC filters are frequently associated with clinically important adverse events, prompting a closer look at their role."[17] Duffett recommends that screening these complications is necessary for all patients, though certain methods of screening may be more ideal in finding different types of filter complications.[18] Hence, if a complication symptom does develop, then that symptom may indicate that a particular type of screening may be more ideal for viewing that particular type of complication. In any event, Duffett unequivocally states that "[i]n patients where an IVC filter remains, regular follow-up to reassess removal and screen for filter-related complications should occur."[19]

Bard also cites Kuo, *et al*.,[20] suggesting that IVC filter patients should be clinically assessed only to determine whether they continue to need IVC filtration, not to check the status of the filter. Br. at 18. This is a misnomer. Kuo states that "The risk of filter fracture increases after 408 days … of implantation and is associated with symptomatic

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[17] Ex. 21, L. Duffett, MD, *Inferior Vena Cava Filters*, 15 J. Thrombosis & Haemostasis 3, 3 (2017).

[18] *Id.* at 7-9.

[19] *Id*. at 3.

[20] Ex. 22, William T. Kuo, MD et al., *Complex Retrieval of Fractured, Embedded, and Penetrating Inferior Vena Cava Filters: A Prospective Study with Histologic and Electron Microscopic Analysis*, 24 J. Vasc. Interv. Radiol. 622 (May 2013).

extravascular penetration and/or intravascular embolization."[21] Kuo does not state that all complications are symptomatic, but nevertheless states that all patients who have received Bard IVC filters "should be evaluated for prompt filter removal if clinically indicated … or they should at least be closely monitored for complications that could then be treated at centers with appropriate expertise."[22] Thus, Kuo suggests that even if a filter is not yet being removed, and even if there are no symptoms present, the ever increasing risks of indwell Bard IVC filters necessitate checking the filter's status.[23]

Neither Duffett nor Kuo support Dr. Morris's opinions that imaging is not necessary to check the status of the filter or to assist in finding potential complications in asymptomatic patients. These studies, along with a number of other bodies of medical literature, recognize the ever increasing risk of implanted Bard IVC filters and recommend imaging and follow-up specifically to find complications and protect patients. Dr. Morris selectively ignored all of these studies in forming his opinions which implore the use of screening to diagnose complications, and therefore his opinions should be excluded.

III. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court grant Plaintiffs' motion to exclude the opinions and testimony of Christopher S. Morris, M.D.

RESPECTFULLY SUBMITTED this 18th day of October, 2017.

GALLAGHER & KENNEDY, P.A.

By: */s/ Mark S. O'Connor*

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[21] *Id.* at 622.

[22] *Id.* at 629-30.

[23] *Id.* at 622.

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of October, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti